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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,200	12/05/2001	Michael R. Wessels	B00801/70237 (ERG/MXA)	8283
7590	02/08/2005		EXAMINER	
Edward R. Gates c/o Wolf, Greenfield & Sacks, P.C. Federal Reserve Plaza 600 Atlantic Avenue Boston, MA 02210-2211			FORD, VANESSA L	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,200

Applicant(s)

WESSELS ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 12-19, 21-23, 45 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-19, 21-23, 45 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 8, 2004 has been entered. Claims 1-3, 23, 45 and 68 have been amended. Claims 9-11, 24-44, 46-67 and 69-162 have been cancelled.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejection Withdrawn

3. In view of Applicant's amendment and response the rejection under 103(a), pages 3-5 of the Final Office action is withdrawn.

Rejection Maintained

4. The rejection under 35 U.S.C. 112 second paragraph is maintained for claims 1-8, 12-19, 21-23, 45 and 68 for the reasons set forth on page 2, paragraph 2 of the Final Office action.

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The rejection was on the grounds that the claims recite the term "reduce the likelihood". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "reduce the likelihood" cannot be ascertained. Clarification as to the meaning of this term is required.

Applicant urges the Examiner agreed that a statistically significant reduction in the likelihood of infection may be determined but the Examiner concludes that the specification does not teach how the determination is made. Applicant urges that determination of reducing likelihood are made routinely in the art. Applicant directs the Examiner to page 22.

Applicant's arguments filed November 8, 2004 have been fully considered but they are not persuasive. The specification does not define the phrase "reduce the likelihood". The specification merely teaches at page 22 that a statistically significant reduction in the likelihood of infection may be determined. The specification does not describe how this determination is made. The claims also recite the phrase "administering orally to a subject in need of such treatment." It is unclear as to what the applicant is referring? Does the phrase "reduce the likelihood of streptococcal infection" mean to prevent infection? Does the phrase "administering orally to a subject in need of such treatment" mean treating a patient that already has a streptococcal infection. The claims are unclear because the preamble appears to recite "preventing streptococcal infections" but yet the method step in the claims recite "treating" subjects that are already have streptococcus infections. The claims are unclear. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8, 12-19, 21-23, 45 and 68 are rejected under 35 U.S.C. 103(a) as unpatentable over Yutaka (*JP 6 107 550, published April 19, 1994*).

Claims 1-8, 12-19, 21-23, 45 and 68 are drawn to a method of treating a subject to reduce the likelihood of streptococcal or staphylococcal infection comprising administering orally to a subject in need of such treatment an agent that binds to a hyaluronic acid-binding region of a CD44 protein in an amount effective to interfere with the adhesion of streptococcal bacteria to CD44 protein in the subject and inhibit streptococcal colonization of the pharynx wherein either one or both of the following conditions applies: the treatment is free of Echinacea or the agent is administered in a dose greater than 0.2 mg wherein the agent is hyaluronic acid.

Yutaka teaches the use of hyaluronic acid for treatment of inflammation of the mucous membrane in amygdalitis, pharyngitis and larynxitis (streptococcal and staphylococcal infections)(see the Abstract). Yutaka teaches that hyaluronic acid can be bonded to the inflammation part of the mucous membrane from the oral cavity to the upper respiratory tract and cure inflammation by oral administration of hyaluronic acid.

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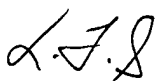
Yutaka teaches a method of treating a subject to reduce the likelihood of streptococcal or staphylococcal infections wherein the treatment is free of Echinacea. It is well within the skill of the art to set dosage requirements, time periods and number of administrations. Therefore, these claim limitations are being viewed as limitations of optimizing experimental parameters”.

Pertinent Prior Art

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure Fillit et al (*Journal of Exp. Med.*, September 1988, p. 971-982 and U.S. Patent No. 4,851,521).

Status of Claims

7. No claims are allowed.


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Conclusion

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vanessa L. Ford
Biotechnology Patent Examiner
February 1, 2005